

MAY 1 8 2000

Premarket Notification (510(k)) Summary

510(k) Number: K001257

Product Name: IntraCoil™ Stent

Common Name: Tracheal prosthesis

Class: II ~~A~~ per 21 CFR 878.3720 (tracheal prosthesis)

Submitter's Name:
IntraTherapeutics, Inc.
651 Campus Drive
St. Paul, MN 55112

Official Contact:
Maria Brittle
Sr. Reg/Clin/Training Associate
Telephone: 651-697-2018
Fax: 651-697-4808

Summary Preparation Date: April 18, 2000

This summary is provided in compliance with section 513(I)(3)(A) of the Act and summarizes the safety and effectiveness information contained in this premarket notification submission. Substantial equivalence is claimed to the IntraTherapeutics, Inc. IntraCoil™ Stent, K990221.

The IntraCoil™ Stent is a self-expanding nickel-titanium (Nitinol) coil premounted on a delivery catheter. The stent is provided in diameters 4 to 8-mm, and lengths of 40 and 60 mm. The intended use is "in the treatment of bronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted." Upon deployment the stent expands to conform to the bronchial lumen surface.

This 510(k) covers addition of the longer length, 60 mm, in diameters 4 to 7 mm. Otherwise, the device is identical to the IntraCoil™ Stent as cleared under K990221. A subset of the *in vitro* performance tests conducted for K990221, and relevant to the stent length, were repeated for design verification and product validation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 18 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Maria E. Brittle
Senior Regulatory/Clinical/Training Associate
IntraTherapeutics, Inc.
651 Campus Drive
St. Paul, Minnesota 55112

Re: K001257
Trade Name: IntraCoil™ Stent
Regulatory Class: II
Product Code: JCT
Dated: April 18, 2000
Received: April 19, 2000

Dear Ms. Brittle:

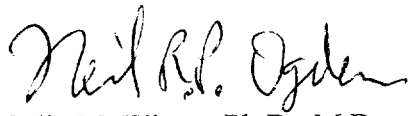
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: IntraCoil™ Stent

Indications for Use:

The IntraCoil™ Stent is indicated for use in the treatment of bronchial strictures produced by malignant neoplasms, or in benign strictures after all alternative therapies have been exhausted.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

MPD for cmw
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 001257

Prescription Use X
(per 21 CFR 801.109)

OR

Over-The-Counter Use ____